C1

1. (Twice Amended) A method of maintaining milk production in a dairy cow fed a low phosphorus diet, comprising the steps of:

feeding as part of a daily diet a feed that contains about 0.3% by weight or less of an inorganic phosphorus supplement to a lactating dairy cow;

feeding with said feed and as part of said daily diet an effective amount of a 1α-hydroxylated vitamin D compound for increasing phosphorus uptake in the cow's gut; and

maintaining said daily diet throughout the cow's lactation period.

REMARKS

In the Office Action dated February 12, 2002, claims 1-7 were examined with the result that all claims were rejected. The Examiner made this rejection final. In response, Applicant has rewritten claim 1. In view of the above amendments and following remarks, reconsideration of this application is requested.

Before turning to the rejections of record, Applicant would like to summarize the amendments made herein to claim 1. Claim 1 now specifically refers to feeding an inorganic phosphorus supplemental "as part of a daily diet to a lactating dairy cow". In addition, claim 1 now states that the vitamin D compound is fed "as part of said daily diet". Finally, claim 1 now also requires that the low phosphorus supplement and the vitamin D compound be fed as part of the animal's daily diet throughout the cow's lactation period. The fact that claim 1 now requires the low phosphorus supplement and vitamin D compound be fed as part of the animal's daily diet and throughout the animal's lactation period distinguishes claim 1 from the prior art cited by the Examiner.

Also, before turning to the argument presented herein, Applicant would like to respond to the Examiner's comments made in the Advisory Action of June 14, 2002. More specifically, the Examiner indicated that the DeLuca et al '312 reference is not limited to dairy cows "in the dry period" and that the example present in the '312 reference is merely a particular example of the method therein. More specifically, the

Examiner refers the Applicant to claim 1. However, Applicant disagrees with the Examiner since claim 1 of the '312 reference specifically states that it relates to a method for "treating dairy cattle for parturient paresis . . ." Claim 1 is thus inherently limited to dairy cows in the dry period since parturient paresis only occurs at the time of parturition. This disease does not occur during a dairy cow's normal lactation period. Thus, claim 1 of the '312 patent is inherently limited to the dry period of dairy cows since the method of claim 1 therein is limited to treating parturient paresis which only occurs in the dry period and following parturition.

In the Office Action, claims 1 and 4-6 were rejected under 35 USC §102(b) as being anticipated by DeLuca et al U.S. Patent 4,338,312. It is the Examiner's position that the '312 reference teaches the administration of 1α-hydroxylated vitamin D compounds together with a low phosphorus diet for use in preventing parturient paresis (milk fever) in dairy cattle. As such, the Examiner believes the '312 reference inherently teaches the method claimed in the present application. Applicant, however, respectfully disagrees for the following reasons.

The Examiner asserts that DeLuca et al '312 broadly discloses a method for treating a dairy cow comprising administering a low phosphorus feed and the instant compounds (see claim 1 of the '312 patent), and the scope of the method disclosed in the '312 patent is nowhere limited to dairy cows only "in the dry period". The Examiner further asserts that the example in column 3 of the '312 reference is merely a particular example of the broad method disclosed therein and does not limit the scope of the method to treating cows only "in the dry period".

Applicant believes, however, that the Examiner's position in this regard is inconsistent with what is actually taught and disclosed in the '312 reference. Further, Applicant believes the Examiner is using hindsight to assert that the '312 reference covers the method of feeding a low phosphorus diet on a regular basis as part of a daily feed to dairy cows. More specifically, the Applicant points to the discussion in the '312 reference at column 2, lines 8-29 therein. The Examiner will note that the discussion therein provides

a partial summary of current treatments for milk fever, and it is to be noted that in each instance the administration of the vitamin D compound is accomplished shortly before parturition, i.e. typically 3-7 days before calving. In particular, the Examiner should note the following statement:

> "If the vitamin D dosage is given too far in advance, the incidence of milk fever disease is actually increased by the treatment."

The only conclusion that can be made from this statement is that one skilled in the art would readily recognize that giving the vitamin D compound to the dairy cow too far in advance of parturition is not good and is undesirable as achieving the opposite results from that which is desired. The only reasonable conclusion to be drawn from this statement is that administering a vitamin D compound in the daily diet of a dairy cow would, in fact, increase the incidences of the disease rather than decrease the incidence of the disease. One skilled in this art would obviously not want to increase the incidence of milk fever. Thus, the '312 patent actually teaches away from administering vitamin D compounds in the daily diet of a dairy cow. As a result, the Examiner's assertion that the DeLuca et al '312 patent teaches administering the instant compounds in the daily diet of dairy cows clearly appears to be inconsistent with what is taught in the '312 reference itself.

To further buttress Applicant's position, it should be noted that nowhere in the description of the '312 patent does it ever state that the vitamin D compounds are to be administered on a daily basis. Instead, the only discussion relating to when the compounds are to be administered can be found in the example as follows:

> "One-half of the cows randomly selected remain untreated whereas the remainder received 0.5mg of 1α-OH-D_3 and 4mg of 25-OH-D_3 dissolved in 5ml of corn oil intramuscularly at least 7 days before the predicted calving date. The cows were re-injected with the same preparation every seventh day for a period of three weeks. Upon successful calving, treatment was discontinued." (*emphasis added*)

The Examiner will note that the example specifically states that the treatment was only given every 7th day and was discontinued after calving was completed. To one skilled in the art, this would mean that the vitamin D compounds were not administered on a daily basis, and clearly the compounds were no longer administered after calving. There is nothing in the '312 reference that the Examiner can point to that states or even implies that the treatment discussed therein was given to dairy cattle as part of their daily diet. In fact, not only does the example refute the Examiner's position, but as discussed previously, the description at column 2, lines 27-29 (relating to not injecting cows too early) also refutes the Examiner's position.

Accordingly, Applicant believes the Examiner should withdraw the rejection based upon the DeLuca et al '312 reference.

In the Office Action, claims 1, 4-5 and 7 were rejected under 35 USC §102(b) as being anticipated by DeLuca et al U.S. Patent 4,110,446. The Examiner once again refers to the broad scope of claim 1 of the '446 patent and its reference to administering 1α,25-dihydroxyvitamin D_3 for the treatment of milk fever disease. The Examiner also asserts that the '446 reference "clearly discloses that the method therein is employed in lactating dairy cows" and refers to Tables 2 and 3 in columns 3 and 4 of the '446 reference. Applicant, however, respectfully disagrees for the following reasons.

Claim 1 of the '446 patent states that sufficient amount of 1α,25-dihydroxyvitamin D_3 must be administered to the cattle in order "to induce said treatment and prophylaxis". As known from the above argument relating to the '312 patent, if one administers the compound too early prior to parturition or calving, incidence of milk fever disease is actually increased by the treatment rather than decreased. Thus, it is clearly inherent in the method of claim 1 that the administration of the vitamin D compound must occur just prior to calving, and not as part of the daily diet of the cattle. If this was not the case, then the administration of the 1α,25-dihydroxyvitamin D_3 compound would not "induce said treatment and prophylaxis", but instead would actually

compound the problem. This same argument can be made with respect to claim 1 of the '312 reference.

It is also important to note that at column 2, lines 37-49 the '446 reference states that administration of 1α,25-dihydroxyvitamin D_3 is effective in preventing milk fever disease

> ". . . when administered from about 24-72 hours before calving occurs. If more than 5 days elapses from the time of administering the first dose and calving has not occurred, an additional dose is generally given . . The use of more than sufficient 1,25-DHCC to accomplish the ends sought should be avoided as an economically unsound practice."

It is clear from these statements that the description in the '446 reference is teaching one skilled in the art that the administration of the vitamin D compound occurs only at a time closely adjacent to parturition or calving and only every 5 days (not daily). Nowhere does the '446 reference teach or suggest that the vitamin D compound could be administered to the dairy cattle together with a low phosphorus diet on a regular basis as part of the daily feed of the cattle. The Examiner's assertion appears to be a hindsight conclusion without any actual support in the description of the '446 patent.

With respect to the Examiner's contention that the DeLuca '446 patent "clearly discloses that the method therein is employed in lactating dairy cows" in accordance with the data in Tables 2 and 3 at columns 3 and 4 therein, Applicant once again believes that the Table itself does not support the Examiner's conclusion. The Examiner appears to be relying upon the fact that the animals being tested are being referred to by their "lactation number" in column 2 of Tables 2 and 3. This "lactation number" does not refer to the fact that cows are lactating, but instead refers to the age of the cows and the number of offspring born by the cow. In other words, it is known that milk fever occurs most often in cows after their third lactation period or third parity (or more) and thus such cows were utilized to obtain the data in Tables 2 and 3. Applicant refers the Examiner to the description in the '312 patent at column 3, lines 9-12 and in the '446 patent at column 4, lines 2-5 wherein reference is made to the fact that cows in their third parity or more were

used in the experiments. Again, this does not mean that they were lactating, but instead refers to their age, i.e. the number of parturitions they have gone through.

In further support of Applicant's position, the Examiner should note that in the third column of Tables 2 and 3 of the '446 reference, the time of injections for each treatment is given. In other words, for animal number 1940H, which was in its fifth parity, it was injected with 1α,25-dihydroxyvitamin D_3 6 days pre-partum and then again 1 day pre-partum. This is consistent with the statement made at column 2, lines 40-42 and column 4, lines 2-5 of the '446 reference. Thus, the animals utilized to obtain the data in Tables 2 and 3 were not "lactating dairy cows", but were instead in their dry period just prior to calving. The "lactation member" clearly relates to the age of the animal being tested and the number of calves previously born by that animal. It has nothing to do with whether the cows were lactating or not.

In view of the above, Applicant believes the Examiner should withdraw the rejection based upon DeLuca et al '446.

In the Office Action, claims 2 and 3 were rejected under 35 USC §103(a) as being unpatentable over DeLuca et al '312 and DeLuca et al '446. Applicant believes, however, that neither of these references anticipate or render obvious claim 1, as now amended, and discussed above. Applicant believes the above comments apply equally to claims 2 and 3 and these claims are believed to be allowable together with claims 1 and 4-7 in view of such comments.

Finally, the Examiner states that the data presented in Applicant's specification do not provide clear and convincing evidence of non-obviousness or unexpected results over the cited prior art. In response, Applicant believes that neither the '312 nor the '446 reference disclose the ability of vitamin D compounds to reduce the phosphorus content of animal waste products or the possible effect on milk production in lactating dairy cows. There is clearly no discussion or suggestion to use a low phosphorus diet in combination with a vitamin D compound on a regular basis as part of the daily feed of a dairy cow. Neither of the references discuss the effects of a low phosphorus diet in

combination with a vitamin D compound on milk production. Thus, Applicant fails to see how either reference teaches or suggests that such a combination may be used to decrease phosphorus in animal feces via the administration of a low phosphorus diet in combination with a vitamin D compound on a regular basis as part of the daily feed for such animals.

Attached hereto is a marked-up version of the changes made to claim 1 by the current Amendment. The attached page is captioned "Version with Markings to Show Changes Made."

An effort has been made to place this application in condition for allowance and such action is earnestly requested.

Respectfully submitted,

ANDRUS, SCEALES, STARKE & SAWALL, LLP

By _____
Thomas M. Wozny
Reg. No. 28,922

Andrus, Sceales, Starke & Sawall, LLP
100 East Wisconsin Avenue, Suite 1100
Milwaukee, Wisconsin 53202
(414) 271-7590
Attorney Docket No.: 1256-00721

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Claim 1 has been rewritten as follows:

1. (Twice Amended) A method of maintaining milk production in a dairy cow fed a low phosphorus diet, comprising the steps of:

feeding as part of a daily diet a feed that contains about 0.3% by weight or less of an inorganic phosphorus supplement to a lactating dairy cow; ~~and~~

feeding with said feed and as part of said daily diet an effective amount of a 1α-hydroxylated vitamin D compound for increasing phosphorus uptake in the cow's gut~~.~~; and

maintaining said daily diet throughout the cow's lactation period.